Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Oxygen Therapy on Patients with Headache Referred to Kashani’s Emergency Room for 15 to 60 Minutes

Protocol summary

Study aim
Determining the effect of oxygen therapy on patients referred to Kashani hospital emergency department for headache for 15 to 60 minutes by visual analog scale (VAS).

Design
Patients will be divided into two intervention and control groups based on a random number table, sample size 60 (30 people in each group), double-blind.

Settings and conduct
This study will be performed in the emergency department of Kashani hospital in Shahrekord.

Participants/Inclusion and exclusion criteria
Age between 18 to 50 years, no mental illness, no brain pathology (brain CT obtained from all patients) or neurological defects in the examination, no high blood pressure, no cancer, no pregnancy or lactation, willingness to cooperate, absence of lung diseases such as asthma, pneumonia, absence of any previous disease being treated.

Intervention groups
Control group: in addition to routine treatment, a mask attached to the air container will be located for the patient. Intervention group, in addition to the painkiller, oxygen therapy will be started with a non-rebreather mask. The amount of oxygen consumed will be at least 15 liters. The amount of pain will be measured and recorded using VAS 0, 15, 30, 45, and 60 minutes after the start of treatment by the patient.

Main outcome variables
Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210907052404N1**
Registration date: **2021-09-25, 1400/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-25, 1400/07/03**
Update count: **0**

Registration date
2021-09-25, 1400/07/03

Registrant information

Name
Mahshid Barzegar Ghahfarokhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3242 4484

Email address
msh_barzegar_gh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-16, 1400/06/25

Expected recruitment end date
2021-11-01, 1400/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Oxygen Therapy on Patients with Headache Referred to Kashani’s Emergency Room for 15 to 60 Minutes

Public title
Effect of Oxygen Therapy on Patients with Headache Referred to Kashani’s Emergency Room for 15 to 60

Minutes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 50 years No brain pathologies (brain CT obtained from all patients) or neurological defects on examination No high blood pressure No cancer No pregnancy and lactation Absence of lung diseases such as asthma, pneumonia Absence of any previous disease to be treated.

Exclusion criteria:

Reluctance to cooperate with the study. Patients with pathological lesions

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into 2 groups equally by Permuted Block Randomization method. In each list, separate blocks of 2 will be placed randomly using a random table of numbers. In each list, the order of treatment is determined and therefore, using the double blocks defined based on the random table, patients will be placed in equal numbers in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both patients and the statistical consultant will not know which group the patients belong to and what type of treatment the other groups will receive.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahre-kord University of Medical Sciences

Street address

Shahrekord, Kashani Blvd., University Headquarters, Building No. 2

City

Shahre-Kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.SKUMS.REC.1398.253

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

Primary outcomes

1

Description

Headache rate measured by AVS.

Timepoint

The amount of pain will be measured and recorded by VAS 0, 15, 30, 45 and 60 minutes after the start of treatment by the patient.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, in addition to painkillers, oxygen therapy will be started by Non-rebreather mask, the amount of oxygen consumed will be at least 15 liters. The amount of pain will be measured and recorded by VAS 0, 15, 30, 45 and 60 minutes after the start of treatment by the patient.

Category

Treatment - Devices

2

Description

Control group: Routine headache treatment will be started for all patients. This treatment will be done with Ketorolac 30 mg ampoules. Each patient will be asked to rate their pain with a visual analog scale (VAS). After

recording the pain, the patient's blood pressure will be measured and recorded, and the O2 sat will be recorded before and after treatment. Also, for the control group, in addition to routine treatment, a mask connected to the air conditioner will be given.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Emergency department of Kashani Hospital in Shahrekord

Full name of responsible person
Mahshid Barzegar Ghahfarokhi

Street address
Shahrekord, Parstar St., Ayatollah Kashani Hospital

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۶۷۵۸۹۱۵

Phone
+98 38 3226 4825

Email
Kashani@skums.ac.ir

Web page address
https://kashanihp.skums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Deputy of research and technology

Street address
Kashani Blvd., University Headquarters, Building No. 2

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Phone
+98 38 3334 2414

Email
vcrt@skums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mahshid Barzegar Ghahfarokhi

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Education

Street address
Nurse St., Ayatollah Kashani Hospital

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۶۷۵۸۹۱۵

Phone
+98 38 3226 4825

Email
msh_barzegar_gh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mahshid Barzegar Ghahfarokhi

Position
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Person responsible for updating data

Contact

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Full name of responsible person
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Phone
+98 38 3226 4825

Email
msh_barzegar_gh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available